UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/423,042	01/19/2000	BRUNO GUY	06132/054001	6264

21559 7590 12/29/2008

CLARK & ELBING LLP
101 FEDERAL STREET
BOSTON, MA 02110

EXAMINER	
PORTNER, VIRGINIA ALLEN	
ART UNIT	PAPER NUMBER
1645	

NOTIFICATION DATE	DELIVERY MODE
12/29/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patentadministrator@clarkelbing.com

Office Action Summary	Application No.	Applicant(s)	
	09/423,042	GUY ET AL.	
	Examiner	Art Unit	
	GINNY PORTNER	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *9/18/2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *5-9,11,15,18, 48; 25,37-38, 40,45-47* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *5-9,11,15,18, 48; 25,37-38, 40,45-47* is/are rejected.

7)☒ Claim(s) *11* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☒ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 5-9,11,15,18, 25,37-38, 40,45-47, and 48 are pending .

Objections/Rejections Withdrawn

1. Withdrawn Claim Objections Claims 15, 18 and 45-46 objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Has been obviated by claim amendment.
2. Withdrawn Claim 39 objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim, has been obviated; the claim has been canceled.
3. Withdrawn Claims 7 rejected under 35 USC 112, second paragraph has been obviated by amending the claim to recite --- further comprises----- and no longer recites the limitation "wherein a TH-type immune response and a TH2- type immune response" in dependence upon claim 6 which only recites the term "Th1-type immune response.
4. Withdrawn Claims, 25, 37-40, and 45-47 rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for induction of an immune response to a Helicobacter pylori polypeptide, and induction of an immune response for reducing the degree of infection (number of colonies) , does not reasonably provide enablement for the administration of any immunogenic agent (any polypeptide) in a method of preventing or treating Helicobacter infection. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in Scope with these claims, has been obviated by claim amendment , in light of the fact.
5. Withdrawn, Claims 25, 37-38, 40, 45-47 rejected under 35 U.S.C. 102(b) as being anticipated by Thomas et al (WO97/02835, publication date January 10, 1997), in light of the claim amendment to recite UreB or UreA of Helicobacter urease with is not specifically taught by Thomas.
6. Withdrawn, Claim Rejections - 35 USC § 102: The rejection of claim 5 under 35 U.S.C. 102(b) as being anticipated by Fulginiti et al (1995) in light of evidence provided Chen et al (1993) and Meyer et al (EP 0835928 (see abstract)) is herein withdrawn in light of the claim amendment to recite strict systemic route.
7. Withdrawn, The rejection of claims 5-6 under 35 U.S.C. 102(e) as being anticipated by Michetti et al (US Pat. 6,290,962; filing date February 23, 1994) in light of evidence provided by Guy et al (1997) is herein withdrawn in light of the amendment of independent claim to recite strict systemic route.
8. Withdrawn, Obviousness-type Double Patenting The rejection of claims 5-9, 14-15, on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-28 of U.S. Patent No. 6,126,938 (common inventor Bruno Guy) is herein withdrawn.
9. The rejection of claim 5 rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, (UreA and UreB are defined to be Helicobacter pylori antigens (see Spec. col. 11, lines 62-63), 13 (mucosal: defined to include anal, vaginal and intragastric , col. 14, lines 19-20), 15

(Intragastrically) and 18 (prophylactic) of U.S. Patent No. 6,379,675, is herein withdrawn in light of Applicant's claim amendments and traversal.

Rejections Maintained/Response to Arguments

10. Applicant's arguments filed September 18, 2008 have been fully considered but they are not persuasive.

Claim Rejections - 35 USC § 112

11. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

12. Maintained Claims 5-9, 15, 18, 48 rejected under 35 U.S.C. 112, first paragraph (scope), because the specification, while being enabling for induction of an immune response to a Helicobacter pylori polypeptide, and induction of an immune response for reducing the degree of infection (number of colonies) , does not reasonably provide enablement for the administration of any immunogenic agent (any polypeptide) in a method of preventing or treating Helicobacter infection. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in Scope with these claims, has been obviated by claim amendment, is traversed on the grounds that references to prevention and treatment have been removed from the claims.

13. It is the position of the examiner that claim 25 and all dependent claims have been amended consistent with Applicant's traversal, and the scope of enablement has been withdrawn over these claims, but independent claim 5 still recites the phrase "a propholactically effective" which is a reference to the prevention of infection. The phrase should be amended to be consistent with Applicant's traversal, and the rejection could be obviated.

Claim Rejections - 35 USC § 102

14. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

15. The rejection of claims 5-6, 11, 15, 18, 48 under 35 U.S.C. 102(b) as being anticipated by WO96/31235 in light of the English version US Patent No 6,126,938, is traversed on the grounds that the claims have been limited to the strict systemic route of administration, which excludes mucosal administration steps.

16. It is the position of the examiner that Guy (WO96' in light of ;938) discloses the claimed methods step of administering a Helicobacter polypeptide antigen by a subdiaphragmetic strict systemic route:

Instant claims 5-6, 15 and 18: " The administration of the first inducing agent may advantageously be carried out in a single dose, by **systemic injection, such as an intravenous, intramuscular, intradermal or subcutaneous injection**. The choice of injection site and route will depend, in particular, on the lymph nodes which it is desired to target. It may be noted that if it is desired, for example, to target the coeliac nodes, it is preferable to perform the injection in the **dorsolumbar region using the** intramuscular route (rather than the subcutaneous route). It is preferable for this inducing agent to be in particulate form. The inducing agent is advantageously supplemented with an adjuvant, either by precipitation or by adsorption. The adjuvant can be any traditional adjuvant of the aluminium phosphate or hydroxide or calcium phosphate type, or

alternatively an adjuvant such as polyphosphazene. It can also be an adjuvant of the liposome, microsphere, ISCOM or virus-like particle (VLP) type; it being especially advantageous to use the latter when it is desired to target the nodes which drain the urogenital region. All these adjuvants are familiar to a person skilled in the art. The appropriate dosage varies in accordance with certain parameters, for example the individual being treated or the nature of the inducing agent. On a point of information, it may be noted that a dose of an antigen can vary from 5 to 100 .mu.g, preferably from 25 to 50 .mu.g. ('938, Col. 5, lines 8-30) " This methods step anticipates the instantly claimed invention as now claimed.

Instant claim 11 : "urease" "For example, in the case of a composition for preventing H. pylori infections, an antigen of choice may be the apoenzyme of the urease, composed of the subunits A and B," (Brief summary paragraph 69); also see (col. 7, lines 30-34)According to a preferred embodiment, the antigen of a bacterium which is pathogenic for the host mammal is an H. pylori antigen, for example the apoenzyme form of H. pylori urease or one of the subunits ureA or ureB of this same urease.

Claim 48: Mammal (col. 19, claim 1) H.pylori human pathogen (inherency) (claims 7-8, Hpylori).

Consistent with the recited claim limitations of independent claim 5, WO96/31235 discloses a method that administers the Helicobacter pylori polypeptide composition by the dorsolumbar route [0041] which is a systemic subdiaphragmatic route of administration. This disclosed embodiment meets the requirement of being administered by the strict systemic route. Guy et al disclose the importance of targeting the celiac nodes for stimulation of a systemic subdiaphragmetic immune response by administering the composition by the dorsolumbar region intramuscularly rather than by a subcutaneous route (see [0041]): "The choice of injection site and route will depend, in particular, on the lymph nodes which it is desired to

target. It may be noted that if it is desired, for example, to **target the coeliac nodes,** it is preferable to perform the injection in the **dorsolumbar region** using the intramuscular route (rather than the subcutaneous route**".**

(Instant claim 15) Guy et al teach the administration of the Helicobacter pylori polypeptide by additional systemic routes of administration to include intravenous, intramuscular, intradermal or subcutaneous injections.

17. Administration of a Helicobacter pylori polypeptide composition by a subdiaphragmatic systemic mucosal route, is disclosed by Guy et al that anticipates independent claim 5:

18. Therefore the mode of administration of Helicobacter pylori polypeptide of Guy et al WO96' is clearly within the scope of the instant claims, and do not change the basic and novel characteristics of the claimed invention because the polypeptide, the source of the antigen, the route of administration, the mammal and the type of immune response stimulated are the same or equivalent as what is now claimed. Guy et al still anticipates the instantly claimed invention as now claimed.

19. Additionally, the examiner that upon reconsideration of the instant Specification found a "nonlimiting illustration" which "consists of" three subcutaneous route, specifically the dorsolumbar region.(See Instant Specification, page 16, paragraph 2, last sentence:

> In this particular case, the administration is said to be of the strict systemic type. By way of a nonlimiting illustration, there may be mentioned a vaccination scheme that consists of administering the urease apoenzyme three times by the subcutaneous route, in the dorsolumbar region, with an interval of two to four weeks between each administration.

20. In light of the fact that the instant claims do not recite "consists", the claimed invention is not limited to what has been described as the strict systemic type of immunization in the instant Specification.

Obviousness Type Double Patenting

21. The rejection of claim 5-8 and 18 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-14 of U.S. Patent No. 6,576,244 (common inventors with instant Application: Weltzin and Bruno Guy) is traversed on the grounds that the '244 patent does not mention administration by "subdiaphragmatic, systemic routes" as required by the claims and the instant claims do not include an adjuvant.

22. It is the position of the examiner that Applicant defines the systemic route to include "the subcutaneous route, the intramuscular route and the intradermal route (see instant claim 18)". US Pat. 6,576,244 administers a composition by a subcutaneous (allowed claim 5) or intradermal route (allowed claim 6), the subcutaneous route being defined in US pat. 6,576,244 to be the lower back (see col. 9, lines 8-14) and the intradermal route being defined to include skin of the back (see '244, col. 9, lines 14-19).

While the claims have been amended to recite the term "primate", and not mammal, the administration to a human by the modes of administration is encompassed by the disclosure in light of the fact that the claimed method of claim 25. A method according to claim 1, wherein the antigen is pathogenic for the mammal, and Helicobacter pylori is pathogenic for humans.

'244 discloses the invention as: Administration The compositions of the invention are administered parenterally; i.e., the composition is injected subcutaneously, intramuscularly, intravenously, intradermally, or **by any other non-mucosal modality.** The LT or CT adjuvant can be administered in an encapsulated form or in an unencapsulated form (i.e., in solution). The methods of the invention can be used both for treatment and prevention

of H. pylori infection. For prevention, the composition is injected into the patient at intervals of one week to six months for a period of between one and six months, at a dosage of 0.05 to 5 mg/kg H. pylori antigen. Where the patient has an H. pylori infection that is to be treated, injections at intervals of one week to six months, for one to six months, are administered, for 0.05 to 5 mg/kg H. pylori antigen. Antibiotics can be administered as an adjunct to the immunotherapy of the invention. The claims still anticipate/render obvious the instantly claimed genus of methods as now claimed.

23. With respect to the allowed claims requiring an adjuvant and the instant claims do not, the instant claims do not exclude compositions that comprise an adjuvant, and the instant Specification teaches the combination of the Helicobacter pylori polypeptides in combination with an adjuvant (see at least page 19 of the instant Specification). Therefore, the allowed method is directed to a species within the instantly claimed genus of methods, because the allowed claims are a species within the instant genus of methods.

New Claim Limitations/New Grounds of Rejection

Priority

24. Acknowledgment is made of applicant's claim for foreign priority based on applications filed in France on 4/30/1997 and 12/08/1997. It is noted, however, that applicant has not filed a certified copy of the French applications as required by 35 U.S.C. 119(b). Upon review of the record, no foreign priority documents were found in the instant Application.

Claim Objections

25. Claim 11 is objected to because of the following informalities: Claim 11 depends from canceled claim 10; the claim is incomplete. Appropriate correction is required.

Claim Rejections - 35 USC § 102

26. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent *in the United States*.

27. Claims 5, 7-9, 11, 15, 18 are rejected under 35 U.S.C. 102(a or b) as being anticipated by Guy et al (Fall 1997, reference of record, Vaccine Research).

28. Guy et al disclose a method that administers Helicobacter pylori polypeptides (see page 146, Table 2, whole cells and urease) to primates (monkeys) for stimulation of a TH2 immune response (see page 148, top of paragraph at bottom of page and serum Ig concentrations, Figure 2, page 147), the method only administering the Helicobacter polypeptide antigens by the intramuscular route, the location being in the lumbar region of the monkey's lower back (see page 143, paragraph 3, last sentence "Intramuscular (im) inoculations were preformed in the muscles of the lumbar region"). Guy et al anticipates the instantly claimed invention as now claimed.

Claim Rejections - 35 USC § 103

29. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

30. Claims 25,37,38,40,45,46,47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Thomas et al (WO97/02835, publication date January 10, 1997, reference of record) in view of WO96/31235 (in light of English translation '938)

Thomas et al teach and describe the instantly claimed method, the method comprising

Instant claim 25: the steps of:

Mucosally (see WO97', page 2, lines 13-17 "mucosal (e.g., intranasal, oral, ocular gastric, rectal, vaginal, gastrointestinal, or urinary tract) administration may precede parenteral (e.g., intravenous, subcutaneous, intraperitoneal, or intramuscular) administration") administering to a mammal (see page 4, line 2 "humans,) in an initial immunization, an effective amount (see page 7, lines 8-11) of Helicobacter pylori (see page 2, line 28) polypeptide antigen (see page 2, lines 25-26; page 7, line 19) and then

Parenterally administering an effective amount of Helicobacter pylori polypeptide antigen (see page 2, lines 23-27) to said mammal (see page 2, lines 15-17).

Instant claim 37: further comprising carrying out more than one mucosal administration (see page 2, lines 18-22 "three weekly doses may be administered mucosally" and on the fourth week, combined mucosal and parenteral administration may be carried out) .

Instant claim 38: further comprising carrying out more than one parenteral administration (see page 11, lines 6-10: "first dose of the vaccine can be administered to a mucosal" surface, and "booster immunization can be administered parenterally"; page 11, lines 23-26, "Administration is repeated as necessary, as can be determined by one skilled in the art. For example, a priming dose can be followed by 3 booster doses at weekly intervals").

Instant claim 40: the mucosal administration is oral (see page 2, lines 13 "oral").
Instant claim 45: administering a mucosal adjuvant in combination (see page 11, lines 15-16 "co-administered") with the Helicobacter pylori antigen (see page 10, lines 19-22).
Instant claim 46: administering a parenteral adjuvant in combination (see page 11, lines 15-16 "co-administered") with the Helicobacter pylori antigen (see page 10, lines 22-24).

Instant claim 47: wherein the parenteral administration is intramuscular (see page 2, line 17) or subcutaneous (see page 11, line 10)

Thomas claims and disclosure:

13. A method of inducing a distal mucosal immune response to a pathogen in a mammal, said method comprising the steps of:

a. administering an antigen capable of inducing said immune response to a mucosal surface of said mammal; and

b. parenterally administering said antigen to said mammal.

The methods of the invention may be used to induce protective and/or therapeutic immune responses to gastrointestinal pathogens including, but not limited to, *Helicobacters* (*e.g.*, *H. pylori*, *H. felis*, and *H. heilmanii*) *Campylobacters* (*e.g.*, *C. jejuni*), and pathogens which cause diarrhea and colitis, e.g., *Clostridia*, enterotoxigenic *E. coli*, Shigella, *Vibrio cholerae*, and *Salmonella typhi*; or genitourinary tract pathogens (*e.g.*, human immunodeficiency virus, herpes simplex viruses, papilloma viruses, *Treponema pallidum*, *Chlamydia*, and *Neisseria gonorrhoeae*). Appropriate vaccine antigens (*e.g.*, polypeptide antigens), corresponding to the pathogen which causes the condition desired to be prevented and/or treated using the method of the invention, are readily selected by one skilled in the art. The methods of the invention are described, as follows, referring to antigens from *C. difficile* (*e.g.*, toxins or toxoids) as specific examples of vaccine antigens which may be used in the methods of the invention.

Thomas teaches the claimed method of stimulating an immune response directed to Helicobacter pylori and states that "Appropriate... antigens

(polypeptide antigens), corresponding to the pathogen which causes the condition desired .... are readily selected by one of skilled in the art" but differs from the instantly claimed invention by failing to show the selected antigens to be UreA or UreB urease antigens .

Guy (WO96 in light of English translation ''938) selected Helicobacter UreA and/or UreB polypeptide antigens for stimulations of an immune response in an analogous art for the purpose of reducing the number of Helicobacter pylori colonies in an individual (WO96, in light of '938: "For example, in the case of a composition for preventing H. pylori infections, an antigen of choice may be the apoenzyme of the urease, composed of the subunits A and B," (Brief summary paragraph 69); also see (col. 7, lines 30-34)According to a preferred embodiment, the antigen of a bacterium which is pathogenic for the host mammal is an H. pylori antigen, for example the apoenzyme form of H. pylori urease or one of the subunits ureA or ureB of this same urease.)

It would have been obvious to the person of ordinary skill in the art at the time the invention was made to modify the method of Thomas that administers Helicobacter pylori polypeptide antigens with the Helicobacter pylori polypeptide UreA or UreB antigens of Guy et al because Guy et al teaches the urease antigens to be highly immunogenic and the immune response is effective in reducing the number of H.pylori colonies.

In the absence of a showing of unexpected results, the person of ordinary skill in the art would have been motivated by the reasonable expectation of success of stimulating an immune response to either one or both of H. pylori UreA or UreB subunits, the immune response being one that Is able to reduce the number of colonies in a human individual because Guy et al showed that these H.pylori polypeptides are highly immunogenic and able to reduce the number of colonies of Helicobacter pylori in an art recognized animal model for H.pylori infection in humans.

Additionally, *KSR International Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1741 (2007), discloses that if a technique has been used to improve one method , and a person of ordinary skill would recognize that it would be used in similar methods in the same way, using the technique is obvious unless its application is beyond that person's skill. *KSR International Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1741 (2007) also discloses that "The combination of familiar element according to known methods is likely to be obvious when it does no more than yield predictable results". It well known in the art to use Helicobacter pylori urease subunits UreA and/or UreB for stimulating an immune response and, together the two references provide a solution to reducing the number of H. pylori colonies infecting an individual, in a manner that allows for reducing the risk of gastric ulcers, malt lymphoma and gastric cancer associated with Helicobacter pylori infection. Thus, it would be obvious to apply a known technique (administration of Helicobacter UreA and/or UreB polypeptides to stimulate an immune response) to a known product (Helicobacter pylori polypeptide antigen) to be used in a known method (stimulation of an immune response) that is ready for improvement of the patient's medical condition .

Conclusion

13. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after

the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

31. Any inquiry concerning this communication or earlier communications from the examiner should be directed to GINNY PORTNER whose telephone number is (571)272-0862. The examiner can normally be reached on flextime, but usually M-F, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Mondesi can be reached on 571-272-0956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Ginny Portner/
Examiner, Art Unit 1645
December 18, 2008

/Mark Navarro/
Primary Examiner, Art Unit 1645